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EXAMINER	
TON, THAIAN N	

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19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/855,587	Applicant(s) SASAI ET AL.	
	Examiner Thaian N. Ton	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-71 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-71 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2, and 12-27, drawn to a method for inducing differentiation of an embryonic stem cell into an ectodermal cell, which comprises culturing the embryonic stem cell under non-aggregation conditions, classified in class 435, subclass 377, for example.

II. Claim 28 drawn to a medium for inducing differentiation of an embryonic stem cell into an ectoderm-derived cell, classified in class 435, subclass 384, for example.

III. Claims 29-31 drawn to a stroma cell-derived factor, which induces differentiation of an embryonic stem cell into an ectodermal or ectoderm-derived cell, classification dependent on agent structure.

IV. Claim 32, drawn to bone morphogenetic protein 4, classified in class 424, subclass 548, for example.

V. Claims 33-36, 60-63, and 66-69 drawn to a stroma cell, which has activity of inducing differentiation of an embryonic stem cell into an ectodermal or ectoderm-derived cell, classification dependent on cell type.

VI. Claims 41 and 42, drawn to a method for obtaining an antibody which specifically recognizes a stroma cell which has activity of inducing differentiation of an embryonic stem cell into an ectodermal or ectoderm-derived cell, which comprises using a stroma cell as an antigen, classified in class 435, subclass 326, for example.

VII. Claim 43-44, 64, and 67-69 drawn to an antibody which specifically recognizes a stroma cell which has activity of inducing differentiation of an embryonic stem cell into an ectodermal or ectoderm-derived cell, classified in class 530, subclass 387.1, for example.

VIII. Claims 48-51, drawn to a method for obtaining a stroma cell-derived factor which has activity of inducing differentiation of an embryonic stem cell into an ectodermal or ectoderm-derived cell, which comprises using, as an index, the activity of inducing differentiation of an

embryonic stem cell into a ectodermal cell, classified in class 435, subclass 377, for example.

IX. Claims 53-54, drawn to a method for increasing purity of a cell that is differentiation-induced from an embryonic stem cell, which comprises culturing the ectodermal or ectoderm-derived cell in a medium comprising an antitumor agent, classification dependent on agent structure.

X. Claims 56-57, drawn to a method for evaluating and/or screening a substance relating to the regulation in a differentiation step from an embryonic stem cell into an ectodermal or ectoderm-derived cell, classified in class 435, subclass 377, for example.

XI. Claims 58-59, drawn to a method for evaluating and/or screening a substance relating to the regulation of the function of an ectodermal or ectoderm-derived cell, classified in class 435, subclass 375, for example.

XII. Claim 70-71 drawn to a method for immunologically detecting the antigen, which comprises using an antibody, classified in class 424, subclass 130.1, for example.

XIII. Claims 3-27 drawn to a method for inducing differentiation of an embryonic stem cell into an ectoderm-derived cell, which comprises culturing the embryonic stem cell under non-aggregation conditions, classified in class 435, subclass 377, for example.

XIV. Claims 37-40 drawn to a culture supernatant obtained by culturing a stroma cell, which has activity of inducing differentiation of an embryonic stem cell into an ectodermal or ectoderm-derived cell, classification dependent on supernatant composition.

XV. Claim 45 drawn to a method for obtaining an antigen recognized by an antibody, which comprises using the antibody, classification dependent on antigen structure.

XVI. Claim 46, 65, and 67-69 drawn to an antigen recognized by an antibody.

XVII. Claim 47 drawn to a medium for culturing a cell, which comprises an antigen, classification dependent on agent structure.

XVIII. Claim 52, 66, and 67-69 drawn to an ectodermal or ectoderm-derived cell, classification dependent on cell type.

XIX. Claim 55 drawn to a cell, classification dependent on cell type.

2. The inventions are distinct, each from the other because of the following reasons:

3. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Inventions II, III, IV, V, VII, XIV, XVI, XVII, XVIII, and XIX are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. Further, the medium of Invention II is independent and distinct from the products of Inventions III, IV, V, VII, XIV, XVI, XVII, XVIII, and XIX because none are required to make the medium composition of Invention II. Further, the stroma cell-derived factor of Invention III is independent and distinct from the products of Inventions II, IV, VII, XIV, XVI, XVII, XVIII, and XIX because none are required to isolate or synthesize the stroma cell-derived factor of Invention III. Bone morphogenetic protein 4 of Invention IV is independent and distinct from the products of Inventions II, III, V, VII, XIV, XVI, XVII, XVIII, and XIX because none are required to isolate or synthesize the protein of Invention IV. The stroma cell of Invention V is independent and distinct from the products of Inventions II,

III, IV, VII, XIV, XVI, XVII, XVIII, and XIX because none are required to isolate or identify the stroma cell of Invention V. The antibody of Invention VII is independent and distinct from the products of Inventions II, III, IV, XIV, XVII, XVIII, and XIX because none are required to isolate or identify the antibody of Invention VII. The culture supernatant of Invention XIV is independent and distinct from the products of Inventions II, III, IV, VII, XVI, XVII, XVIII, and XIX because none are required to make or use the culture supernatant of Invention XIV. The antigen of Invention XVI is independent and distinct from the products of Inventions II, III, IV, V, XIV, XVIII, and XIX because none are required to make or use the antigen of Invention XVI. The medium of Invention XVII is independent and distinct from the products of Inventions II, III, IV, V, VII, XIV, XVIII, and XIX because none are required to make the medium composition of Invention XVII. The ectodermal or ectoderm-derived cell Invention XVIII is independent and distinct from the products of Inventions II, III, IV, V, VII, XIV, XVI, XVII, and XIX because none are required to isolate or identify the ectodermal or ectoderm-derived cell of Invention XVIII. The cell Invention XIX is independent and distinct from the products of Inventions II, III, IV, V, VII, XIV, XVI, XVII, and XVIII because none are required to isolate or identify the cell of Invention XIX. Further, the stroma cell-derived factor of Invention III can be prepared by processes which are materially different the stroma cell of Invention V, such as by chemical synthesis, or by isolation and purification from natural sources. The stroma cell of Invention V can

be used in materially different methods other than to make the antibody of Invention VII, such as in therapeutic or diagnostic methods (e.g., in screening). Although the stroma cell of Invention V can be used to manufacture the culture supernatant of Invention XIV it can also be used in materially different methods, such as in various diagnostic (e.g., as a probe in immunoassays or immunochromatography), or therapeutic methods. Although the antigen of Invention XVI can be used to manufacture the medium of Invention XVII it can also be used in materially different methods, making antibodies. Finally, although the antibody of Invention VII can be used to obtain the antigen of Invention XVI it can also be used in materially different methods, such as in various diagnostic (e.g., as a probe in immunoassays or immunochromatography), or therapeutic methods. The antibody of Invention VII can be used in materially different methods other than to identify the stroma cell of Invention V, such as in therapeutic or diagnostic methods (e.g., in screening). The culture supernatant of Invention XIV can be prepared by processes which are materially different from incubation with the stroma cell of Invention V, such as by chemical synthesis, or by isolation and purification from natural sources. The antigen of Invention XVI can be prepared by processes, which are materially different from using the antibody of Invention VII, such as by chemical synthesis, or by isolation and purification from natural sources. The medium of Invention XVII can be prepared by processes, which are materially

different from using the antigen of Invention XVI, such as by chemical synthesis, or by isolation and purification from natural sources.

4. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Inventions I, VI, VIII-XIII, and XV are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention I requires search and consideration of culturing an embryonic stem cell under conditions to induce its differentiation into an ectodermal cell, which is not required by any of the other groups. Invention VI requires search and consideration of utilizing a stroma cell as an antigen to obtain an antibody, which is not required by any of the other groups. Invention VIII requires search and consideration of a method for obtaining a stroma cell-derived factor, which is not required by any of the other groups. Invention IX requires search and consideration of a method for increasing purity of a cell population, which is not required by any of the other groups. Invention X requires search and consideration of the regulation of a differentiation step of an ectodermal cell, which is not required by any of the other groups. Invention XI requires search and consideration of the regulation of the function of an ectodermal cell, which is not required by any of the other groups. Invention XII requires search and consideration of a method for immunologically detecting an antigen, which is not

required by any of the other groups. Invention XIII requires search and consideration of culturing an embryonic stem cell under conditions to induce its differentiation into an ectoderm-derived cell, which is not required by any of the other groups. Invention XV requires search and consideration of a method for obtaining an antigen, which is not required by any of the other groups. Therefore, a search and examination of all of the methods in one patent application would result in an undue burden, since the searches for the methods are not co-extensive, the classification is different, and the subject matter is divergent.

5. Inventions II and each of XIII and I are related as product and processes of making. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process. The medium of Invention II could be synthesized from natural and manufactured materials.

6. Inventions III and VIII are related as product and process of making. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made

by another and materially different process. The stroma cell-derived factor of Invention III could be isolated from its natural source.

7. Inventions V and each of I, VI, X, XI, and XIII are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product. The stroma cell of Invention V can be used to screen stroma cell-specific apoptosis factors.

8. Inventions VII and VI are related as product and process of making. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process. The antibody of Invention VII could be made using polypeptides from stroma cell library to antigenize an animal or hybridoma culture.

9. Inventions XVI and XV are related as product and process of making. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2)

that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process. The antigen of Invention XVI could be used to isolate screening compounds that bind the antigen.

10. Inventions XVII and XV are related as product and process of making. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process. The antigen of the medium of Invention XVII could be chemically synthesized.

11. Inventions XIX and IX are related as product and process of making. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process. The cell of Invention XIX could be isolated from its natural source.

12. Inventions II and each of VI, VIII, IX, X, XI, XII, and XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or

different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Groups II and each of VI, VIII, IX, X, XI, XII, and XV are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions VI, VIII, IX, X, XI, XII, and XV do not recite the use or production of the medium of Invention II.

13. Inventions III and each of I, VI, IX, X, XI, XII, XIII, and XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Groups III and each of I, VI, IX, X, XI, XII, XIII, and XV are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions I, VI, IX, X, XI, XII, XIII, and XV do not recite the use or production of the stroma cell-derived factor of Invention III.

14. Inventions IV and each of I, VI, VIII, IX, X, XI, XII, XIII, and XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Groups IV and each of I, VI, VIII, IX, X, XII, XIII, and XV are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions I, VI, VIII, IX, X, XII, XIII, and XV

do not recite the use or production of the bone morphogenetic protein 4 of Invention IV.

15. Inventions V and each of VIII, XII, XIII, and XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Groups V and each of VIII, IX, XII, XIII, and XV are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions VIII, IX, XII, XIII, and XV do not recite the use or production of the stroma cell of Invention V.

16. Inventions VII and each of I, VIII, IX, X, XI, and XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Groups VII and each of I, VI, VIII, IX, X, XI, and XIII are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions I, VI, VIII, IX, X, XI, and XIII do not recite the use or production of the antibody of Invention VII.

17. Inventions XIV and each of I, VI, VIII, IX, X, XI, XII, XIII, and XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different

functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Groups XIV and each of I, VI, VIII, IX, X, XI, XII, XIII, and XV are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions I, VI, VIII, IX, X, XI, XII, XIII, and XV do not recite the use or production of the culture supernatant of Invention XIV.

18. Inventions XVI and each of I, VI, VIII, IX, X, XI, XII, and XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Groups XVI and each of I, VI, VIII, IX, X, XI, XII, and XIII are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions I, VI, VIII, IX, X, XI, XII, and XIII do not recite the use or production of the antigen of Invention XVI.

19. Inventions XVII and each of I, VI, VIII, IX, X, XI, XII, and XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Groups XVI and each of VI, XII, and XV are unrelated product and methods, wherein each is not required, one for another. For example, the claimed

methods of Inventions VI, XII, and XV do not recite the use or production of the antigen of Invention XVII.

20. Inventions XVIII and each of VI, XII, and XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Groups XVI and each of VI, XII, and XV are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions VI, XII, and XV do not recite the use or production of the antigen of Invention XVIII.

21. Inventions XIX and each of I, VI, VIII, X, XI, XII, XIII, and XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Groups XIX and each of I, VI, VII, VIII, X, XI, XII, XIII, and XV are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions I, VI, VII, VIII, X, XI, XII, XIII, and XV do not recite the use or production of the cell of Invention XIX.

22. Inventions I and each of IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with

another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the products as claimed can be used in a materially different process of using that product. The active ingredient of Invention IV, bone morphogenetic protein 4 can be used to radiolabel receptors. The stroma cell in Invention V can be used to make antigens for Invention VI.

23. Inventions IX and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process. The cells described in V could be isolated via high-throughput screening procedure using specific antigen expression to identify them.

24. Inventions VII and XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of

using that product. Invention VII, can be used a medicament as described in Claims 60-69.

25. Inventions XV and VII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process. The antibody of Invention VII can be produced via antigenization of an animal such as a rabbit against a stroma cell.

26. Inventions XVIII and each of I, VIII, IX, X, XI, and XIII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process. An ectodermal or ectoderm-derived cell could be isolated from its natural source.

27. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, and/or different classification, restriction for examination purposes as indicated is proper.

28. This application contains claims directed to the following patentably distinct species of the claimed invention:

a. Nervous system cell

b. Epidermal cell

29. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-71 are generic.

30. If applicant selects any one of the Inventions I-XIX, one species from the cell type group must be chosen to be fully responsive.

31. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

32. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

33. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record

showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

34. This application contains claims directed to the following patentably distinct species of the claimed invention:

c. Ectodermal cell

d. Ectoderm-derived cell

35. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-71 are generic.

36. If applicant selects any one of the Inventions I-XIX, one species from the embryonic stem cell type group must be chosen to be fully responsive.

37. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

38. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37

CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

39. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

40. This application contains claims directed to the following patentably distinct species of the claimed invention:

e. A neural stem cell

f. A nerve cell

g. A cell of neural tube

h. A cell of neural crest

41. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 6 is generic.

42. If applicant selects any one of the Inventions I-XIX, one species from the nervous system cell type group must be chosen to be fully responsive.

43. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a

listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

44. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

45. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

46. This application contains claims directed to the following patentably distinct species of the claimed invention:

i. A dopaminergic neuron

j. An acetylcholinergic neuron

k. A γ-aminobutyratergic neuron

l. A serotonergic neuron

47. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 8 is generic.

48. If applicant selects any one of the Inventions I-XIX, one species from the nerve cell type group must be chosen to be fully responsive.

49. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

50. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

51. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

52. This application contains claims directed to the following patentably distinct species of the claimed invention:

m. A cell of neural tube before determination of dorso-ventral axis, which is capable of differentiating into a cell positioned at the ventral side by reacting with sonic hedgehog as a ventral factor of neural tube and of differentiating into a cell positioned at the dorsal side by reacting with bone morphogenetic protein 4 as a dorsal factor of neural tube

n. A cell of the neural tube ventral side, expressing HNF-3β (hepatocyte nuclear factor-3β) positioned on the basal plate of the most ventral side of neural tube

o. A cell of the neural tube ventral side, expressing a marker Nkx2.2 existing secondary to the HNF-3β (hepatocyte nuclear factor-3β) from the ventral side of neural tube

p. A cell of the neural tube dorsal side, expressing Pax-7

53. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 10 is generic.

54. If applicant selects any one of the Inventions I-XIX, one species from the cells of the neural tube type group must be chosen to be fully responsive.

55. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a

listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

56. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

57. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

58. This application contains claims directed to the following patentably distinct species of the claimed invention:

q. Bone morphogenetic protein 4

r. Sonic hedgehog

s. Stroma cell-derived factor

t. Stroma cell

59. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-71 are generic.

60. If applicant selects any one of the Inventions I-XIX, one species from the protein culture group must be chosen to be fully responsive.

61. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

62. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

63. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

64. This application contains claims directed to the following patentably distinct species of the claimed invention:

u. A treatment with an antitumor agent

v. A treatment by an radiation irradiation

w. A treatment for tissue fixation used in pathologic diagnosis, whether;

65. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 19 is generic.

66. If applicant selects any one of the Inventions I-XIX, one species from the physiochemical treatment group must be chosen to be fully responsive.

67. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

68. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

69. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

70. This application contains claims directed to the following patentably distinct species of the claimed invention:

i. Mitomycin C

ii. 5-fluorouracil

iii. Adriamycin

iv. Methotrexate

v. Ara C

71. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 20 is generic.

72. If applicant selects any one of the Inventions I-XIX, one species from the antitumor agent group must be chosen to be fully responsive.

73. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An

argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

74. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

75. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

76. This application contains claims directed to the following patentably distinct species of the claimed invention:

x. Microwave fixation

y. A rapid freeze-substitution fixation

z. A gluteraraldehyde fixation

aa. A p-formaldehyde fixation

bb. A formalin-fixation

cc. An acetone fixation

dd. A Van fixation

ee. A periodic acid fixation

ff. A methanol fixation, OR

gg. An osmic acid fixation

77. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 21 is generic.

78. If applicant selects any one of the Inventions I-XIX, one species from the treatment for tissue fixation group must be chosen to be fully responsive.

79. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

80. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

81. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record

showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

82. This application contains claims directed to the following patentably distinct species of the claimed invention:

hh. A fetal primary culture fibroblast

ii. An SIHM mouse-derived STO cell

jj. A mouse fetus-derived NIH/3T3 cell

kk. An M-CSF deficient mouse calvaria-derived OP9 cell

ll. A mouse calvaria-derived MC3T3-G2/PA6 cell

mm. An embryonic stem cell-derived stroma cell, OR

nn. A bone marrow mesenchymal stem cell-derived stroma cell

83. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 23 is generic.

84. If applicant selects any one of the Inventions I-XIX, one species from the stroma cell type group must be chosen to be fully responsive.

85. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An

argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

86. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

87. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

88. This application contains claims directed to the following patentably distinct species of the claimed invention:

oo. An embryonic stem cell established by culturing an early embryo before implantation,

pp. An embryonic stem cell established by culturing an early embryo produced by nuclear transplantation of the nucleus of a somatic cell

qq. An embryonic stem cell in which a gene on the chromosome of the embryonic stem cell of (o) or (p) is modified using a gene engineering technique

89. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 24 is generic.

90. If applicant selects any one of the Inventions I-XIX, one species from the more specific embryonic stem cell type group must be chosen to be fully responsive.

91. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

92. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

93. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is

the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

94. This application contains claims directed to the following patentably distinct species of the claimed invention:

rr. Disorder of a nervous system cell

ss. Disorder of an epidermal system cell

95. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 68 is generic.

96. If applicant selects any one of the Inventions I-XIX, one species from the disorder of an epidermal system cell group must be chosen to be fully responsive.

97. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

98. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37

CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

99. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

100. This application contains claims directed to the following patentably distinct species of the claimed invention:

tt. Alzheimer disease

uu. Huntington chorea

vv. Parkinson disease

ww. Ischemic cerebral disease

xx. Epilepsy

yy. Brain injury

zz. Vertebral injury

aaa. Motor neuron disease

bbb. Neurodegeneration disease

ccc. Pigmentary retinal dystrophy

ddd. Cochlear hearing loss

eee. Multiple sclerosis

fff. Amyotrophic lateral sclerosis

ggg. Disease due to a neurotoxin damage

101. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 67-69 are generic.

102. If applicant selects any one of the Inventions I-XIX, one species from the disorders of a nervous system cell group must be chosen to be fully responsive.

103. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

104. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

105. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is

the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

106. This application contains claims directed to the following patentably distinct species of the claimed invention:

hhh. Burn

iii. Wound

jjj. Compression gangrene

kkk. Psoriasis

107. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 67-69 are generic.

108. If applicant selects any one of the Inventions I-XIX, one species from the disorders of an epidermal system cell group must be chosen to be fully responsive.

109. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

110. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or

otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

111. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

112. If Applicant selects any one of Inventions I-XIX, one species from each of the following groups must be chosen to be fully responsive:

(1) Cell type

(2) Embryonic stem cell type

(3) Nervous system cell type

(4) Nerve cell type

(5) Cells of the neural tube type

(6) Protein culture group

(7) Physiochemical treatment

(8) Antitumor agent

(9) Treatment for tissue fixation

(10) Stroma cell type

(11) Specific embryonic stem cell type

(12) Disorder of an ectoderm-derived system cell

(13) Disorders of a nervous system cell

(14) Disorders of an epidermal system cell

113. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thaian N. Ton whose telephone number is (703) 305-1019. The examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off. Should the examiner be unavailable, inquiries should be directed to Deborah Reynolds, Supervisory Primary Examiner of Art Unit 1632, at (703) 305-4051. Any administrative or procedural questions should be directed to Patsy Zimmerman, Patent Analyst, at (703) 305-2758. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703)872-9306.

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